REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action dated December 30, 2003. Claims 1, 6 and 8 have been amended, without intending to abandon or to dedicate to the public any patentable subject matter. Claims 10-14 are new. Accordingly, Claims 1-14 are now pending. As set out more fully below, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Claims 1-3 and 5 stand rejected under 35 U.S.C. § 101 on the grounds that the invention claimed therein is directed to non-statutory subject matter. Applicants' respectfully traverse these rejections. In particular, pending Claims 1-3 and 5 apply, involve, use, or advance the technological arts, for at least the reason that the claimed invention is tied to a computer implemented database, and because Claims 1-3 and 5 provide a method that is useful in the tracking of samples of a clinical study. (*Cf. Ex parte Bowman*, 61 USPQ2d.1669,1671 (Bd. Pat. App. and Int. 2001) (unpublished)(holding that manually drawing or creating a chart was nothing more than an abstract idea, and was not tied to any technological art, environment or machine)). In particular, according to Claims 1-3 and 5, identifying information for samples comprising biological material is recorded in a computer implemented database, a worklist is created that includes a first set of samples recorded in the database, a first checklist is displayed, a completion status of the steps on the checklist is recorded in the database, a query of the database for a status of at least a first sample is initiated, and a report that includes at least some of the completion status or results stored in the database is generated. Accordingly, the Applicants submit that the rejections under 35 U.S.C. § 101 should be reconsidered and withdrawn.

The Office Action notes that the claim limitations have been given their ordinary and accustomed meaning. Applicants note that certain claimed terms have been alternately and/or further defined, for example in dependent claims, as set forth in those claims and/or as supported by the disclosure of the specification.

The Office Action includes a requirement for information. Materials submitted in response to the requirement for information are attached hereto as Exhibit A. The submitted materials are a good faith effort to completely respond to the requirement.

Claims 6 and 8 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,898,586 to Jeatran et al. ("Jeatran"). In order for a rejection under 35 U.S.C. § 102 to be proper, each and every element as set forth in a claim must be found, either expressly or inherently described, in a single prior art reference. (MPEP Section 2131). However, each and every element of the claims cannot be found in the Jeatran reference. Therefore, reconsideration and withdrawal of the rejections of Claims 6 and 8 are respectfully requested.

Claim 6 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 6, a list of standard operating procedures comprising procedure steps of laboratory procedures to be performed on at least some samples of biological material is provided, as is a list of samples. Claim 6 further recites that the list of standard operating procedures is merged with the list of samples to generate a checklist for use in connection with the clinical study. In addition, a report including a status of the list of samples is displayed. As explained more fully below, Jeatran is directed to distributing clinical trial

materials to patients. Accordingly, Jeatran does not describe a method that includes providing lists comprising laboratory procedures to be performed on samples of biological material.

Claim 8 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 8, a plurality of biological samples are accessioned, and procedures to be taken with respect to the biological samples are determined. In addition, Claim 8 recites defining at least a first work group comprising at least a first of the plurality of biological samples, wherein the first work group comprises at least one procedure to be performed on at least one of the biological samples. The procedures each comprise a plurality of steps. As recited by amended Claim 8, the method further includes displaying the checklist, performing the steps, and recording performance of the steps in the computer as the steps are performed. As noted more fully below, the Jeatran reference is related to clinical studies, and does not involve the performance of procedures taken with respect to biological samples that comprise a plurality of steps. In addition, Jeatran does not describe displaying a checklist or recording the performance of the steps of a procedure as those steps are performed. Therefore, for at least these reasons, the rejection of Claim 8 as anticipated should be reconsidered and withdrawn.

The Jeatran reference is generally directed to a method for administering clinical trial material. In particular, Jeatran attempts to reduce the wastage of medications used in clinical trials, by providing an alternative to the prior art method of conducting such trials, which according to Jeatran includes providing kits consisting of each possible dosage that may be needed by a patient during the study. (See Jeatran, col. 1, ln. 64 - col. 2, ln. 3). The method

discussed by Jeatran includes providing a computer means that, when contacted by an investigator, is operable to identify which of a plurality of bottles of clinical material is to be disseminated to an identified patient. Confirmation of the identity of patients and the disseminated medication can be made by having the investigator enter patient identification numbers and other information (Jeatran, col. 8, lns. 30-64), check received materials and verify that all information is present (col. 11, lns. 41-60), confirm the assignment of previously assigned medication (col. 11, lns. 64-66), and administer the patient status (col. 12, lns. 28-52). Accordingly, it can be appreciated that Jeatran is directed to controlling the distribution of medication to patients by an investigator to assist in conducting blind clinical trials, without any of the investigators, patients or sponsors knowing when or what medication or randomization changes are occurring. (Jeatran, col. 14, lns. 1-16). However, Jeatran does not describe defining or providing a list of procedures to be performed on samples of biological material or of generating reports as generally set forth in pending Claims 6 and 8.

Claims 7 and 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jeatran in view of an article by Evans and Relling ("Evans"); Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jeatran; Claim 2 stands rejected under 35 U.S.C. § 103 as being unpatentable over Jeatran in view of U.S. Patent No. 5,675,745 to Oku et al. ("Oku") and further in view of an article by Kennedy ("Kennedy"); and Claim 4 stands rejected under 35 U.S.C. § 103 as being unpatentable over Jeatran in view of Evans. In order to establish a *prima facie* case of obviousness under Section 103, there must be some suggestion or motivation to modify the reference or to combine the reference teachings, there must be a reasonable

expectation of success, and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP Section 2143). It is submitted that the cited references do not teach, suggest or disclose each and every element as set forth in the claims. For example, the cited references do not teach, suggest or disclose a method according to which work lists comprising sets of biological samples and checklists of procedures to be performed with respect to those samples are provided. In addition, Applicants note that the Office Action does not provide any suggestion or motivation for making the various proposed combinations of references, and that even if the proposed combinations are proper, such combinations do not teach or suggest all of the claim limitations. Accordingly, the rejections of Claims 1-5, 7 and 9 as obvious should be reconsidered and withdrawn.

Claim 7 depends from Claim 6, and recites that at least one of the procedures performed on at least some samples of biological material determines the genotype of an individual. Claim 9 depends from Claim 8, and also recites that at least one of the procedures performed determines the genotype of an individual. As noted in the Office Action, Jeatran does not teach, suggest, or disclose a procedure that includes determining the genotype of an individual. Furthermore, as noted above, Jeatran does not describe providing a list of standard operating procedures that comprise procedure steps of laboratory procedures to be performed on at least some samples of biological material or generating a checklist by merging the list of standard operating procedures with the list of samples, as generally recited by Claim 6. As also noted above, Jeatran does not teach, suggest or disclose accessioning a plurality of biological samples, determining procedures to be taken with respect to the biological samples, defining at least a first

workgroup comprising a least a first of the biological samples, preparing at least one checklist, displaying the checklist, performing the steps, and recording performance of the steps as the steps are performed, as generally recited by Claim 8.

The Evans reference, cited by the Office Action in connection with the rejections of Claims 7 and 9, discusses how inherited characteristics affect the efficacy and toxicity of many medications with respect to individual patients. However, Evans does not teach, suggest or disclose performing a procedure included in a checklist to determine the genotype of an individual on a sample of biological material that is included in a workgroup. Furthermore, Evans does not teach, suggest or disclose a method that includes generating a checklist of procedures to be performed on samples as claimed, or other of the elements of Claims 6 and 8 that are not described by Jeatran. Therefore, the rejections of Claims 7 and 9 should be reconsidered and withdrawn.

Claim 1 is generally directed to a method for tracking samples of a clinical study. According to Claim 1, a first clinical study protocol comprising a plurality of procedures is defined, in which the procedures comprise steps of laboratory procedures to be performed on at least some samples comprising biological material. Samples comprising biological material are accessioned by recording identifying information in a computer implemented database. A first worklist is created by assigning a first scientist to perform at least a first procedure on a first set of samples recorded in the database. A first checklist comprising steps of at least a first procedure to be performed on the samples of the first worklist is created and the first checklist is displayed to the first scientist, wherein the first scientist performs the steps of the first checklist.

Claim 1 further recites recording in the database a completion status and results of at least a portion of the steps on the first checklist. The method of Claim 1 additionally includes initiating a query of the database for a status associated with at least a first of the accession samples, and generating a report in response to the query. The report includes at least some of the completion status or results stored in the database, wherein a status of the at least a first of the accessioned samples is tracked.

As noted elsewhere herein, the Jeatran reference is directed to administering clinical trial material. Accordingly, Jeatran does not teach, suggest or disclose defining a protocol comprising a plurality of procedures that comprise laboratory procedures to be performed on at least some samples comprising biological material, or accessioning samples comprising biological material. Instead, Jeatran discusses distributing clinical material to patients. In addition, Jeatran does not teach, suggest or disclose creating a first worklist or a first checklist comprising steps of a procedure to be performed or displaying the checklist to a first scientist, and recording completion of the steps. Furthermore, there is no teaching, suggestion or disclosure in Jeatran of initiating a query of the database, or generating a report in response to a query that tracks a status of at least a first sample.

Claim 3 depends from Claim 1, and additionally recites that the step of indicating completion and results of at least a portion of the steps on the checklist comprises indicating completion of at least one step for all samples on a checklist by one entry of information. This is contrary to Jeatran, which discusses entering information related to individual patients, or related

to particular clinical material received for distribution. Accordingly, for at least these additional reasons, Claim 3 is not obvious in view of Jeatran.

Claim 5 depends from Claim 1 and additionally recites formalization of the results by an activity selected from the group consisting of: inspection of results; inspection of chain of custody records; entry of new results; inspection of procedures run; and modification and rejection of erroneous results. There is no teaching, suggestion or disclosure of formalizing results as recited by Claim 5. Accordingly, for these additional reasons, Claim 5 is not obvious in view of Jeatran.

Claim 2 depends from Claim 1, and additionally recites performing a second clinical study protocol in connection with the elements recited by Claim 1 in which a worklist assigned to a particular scientist comprises at least one sample associated with the first clinical study protocol and at least a second sample is associated with the second clinical study protocol. As noted above, Jeatran does not teach, suggest or disclose all of the elements recited by Claim 1. In addition, the Oku and Kennedy references, which are additionally recited in connection with the rejection of Claim 2, do not make up the deficiencies of Jeatran. In particular, Oku, which is generally directed to a method for organizing workflow using a database, discusses high level time tables associated with clinical studies and standards of operation. Oku is cited in the Office Action for teaching that multiple clinical trials can be contained within the same system, and that work management can be entered as assigned to a specific person for a specific task. However, Oku does not teach, suggest or disclose generating a work list concerning at least a first procedure performed on samples associated with first and second clinical protocols. In

particular, the figure referenced in the Office Action with respect to the assignment of procedures to a specific person is related to a clinical trial report, and there is no teaching, suggestion or disclosure in Oku that such a clinical trial report is related to different clinical study protocols. (Oku, Figure 54). The Kennedy reference is cited with respect to the rejection of Claim 2 for assigning one person to more than one project team. However, this is not the same as creating a checklist of procedures that are performed on samples from different protocols. Accordingly, the rejection of Claim 2 as obvious should be reconsidered and withdrawn.

Claim 4 depends from Claim 1 and additional recites that at least one of the procedures determines the genotype of an individual. As noted above, Jeatran does not teach, suggest or disclose each and every element recited by Claim 1. In addition, the Evans reference cited in the Office action in connection with the rejection of Claim 4 does not supply the elements missing from Jeatran with respect to Claim 1. Furthermore, although Evans discusses the effect of inherited differences on an individual's response to medications, Evans does not teach, suggest or describe performing a step of determining the genotype of an individual as part of a method for tracking biological samples of a clinical study.

New claims 10-14 depend from Claim 1. Therefore, claims 10-14 are allowable for at least the same reasons that Claim 1 is allowable. In addition, Claims 10-14 each recite additional patentable elements, and should also be allowed for reciting such additional elements.

The application now appearing to be in form for allowance, early notification of same is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite the resolution of this case.

Respectfully submitted,

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